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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/280,279	03/29/1999	JON M. MILLER	MILLER.P001	5533

7590 06/15/2005

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/280,279	MILLER, JON M.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on February 04, 2005 has been entered. Claims 29-39 are pending.

The effective filing date for this Application is March 29, 1999. Applicant's arguments filed on February 04, 2005 have been fully considered but are not found persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 29-31, 33-37, 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ritter US Patent 4,293,562.

3. Ritter administers cimetadine, an H2 Antagonist, with an anorexant such as dextroamphetamine, phenteramine or phenmetrazine. Ritter uses this combination to suppress the appetite of a mammal as an adjunct to weight control. (abstract, col 4-6). The amphetamines used by Ritter are viewed to fall within the scope of the instant "mood altering" and "psychotropic agents" because they exert a central effect upon the mind or are able to modify mental activity of the patients who takes them. For example, Ritter clearly states that amphetamine can cause CNS stimulation (see col 1, lines 35-55; col 2, lines 34-36). Ritter also claims dosage forms that comprise both the cimetadine and the anorexant. (see claims 1,4,5). Ritter's patients are viewed to be in need of an anorexant because they are taking such drug during their course of treatment. Ritter uses his combination for treating eating disorder that falls within the

scope of the instantly recited limitations "depressive illness or impulse-control disorders and the related conditions." Thus, Ritter anticipates all limitations of the instant claims.

4. Applicant's arguments with respect to this rejection are not persuasive. Applicant argues that Ritter uses an anorexant also known as "appetite suppressants" in combination with H2-antagonists. (*see* Arguments at page 9). Applicant then adds that anorexants are amphetamines or non-amphetamine compositions not within the scope of the instant limitations "mood altering or psychotropic drugs" especially for treatment of schizophrenia, other psychoses, bipolar disorder, impulse-control disorders and related conditions. (*see* Arguments at page 10).

5. In response Examiner states that Applicant's arguments are not commensurate with the scope of the rejected claims. First, Examiner points out that during patent examination, the pending claims are given the broadest reasonable interpretation consistent with the art and or specification. See MPEP 2111. Accordingly, amphetamine is viewed to fall within the genus of "psychotropics or mood altering agents." Second, contrary to Applicant's assertions neither the art, nor the specification, excludes the amphetamines described in Ritter from the instantly employed limitations of "psychotropic active compounds" or "mood altering drugs." Third, Ritter meets all elemental and manipulative steps of instant claims, thus, it inherently anticipates all functional goals or limitations of the instant claims. Accordingly, for such reasons the rejection is maintained.

The instant claims are directed to methods that employ an open-ended transition phrase "comprising" and further is limited to administering a psychotropic active

compound and an effective amount of an H2 antagonist. Ritter meets such limitations by describing methods of administering a patient amphetamine and an H2 blocker. (see abstract). Applicant argues that amphetamines are not considered "mood altering or psychotropic agents" because they are classified in a different class than psychotropic drugs. Applicant offers copies of pages 203-205 of Physicians Desk References 1994 (PDR 94) to support the argument that appetite suppressants are classified in an entirely different class as antipsychotic or psycotropic drugs.(*see* Arguments at page 10).

In response Examiner state that the PDR 94 does neither expressly nor impliedly establish Applicant's conclusion. A fair reading of PDR 94 at page 203 states that information about anorexants and sympathomimetics can also bee found under the heading "appetite suppressants." PDR 94 then at page 205 provides that the information about antipsychotic medications are under the heading "psychotropics." There is no statement in PDR 94 establishing that "appetite suppressants" are not within the scope of psychotropic compounds or mood altering drugs.

In fact, Examiner offers different pages of the 1997 version of PDR to support his position that in fact amphetamine falls within the instant term "psychotropic or mood altering agent." The PDR 97 at page 216 recognizes various subheadings under the main heading of "Psychotherapeutic Agents" (or psychotropics). Attention is drawn to this page at 2nd, 3rd and 4th columns. Accordingly, information about Psychotherapeutic or Psychotropic Agents are available under the subheadings antianxiety agents, antidepressants, antimanic agents, antipanic agents, antipsychotic agents, obsessive

compulsive disorder management, and psychostimulants. The PDR 97 then refers the interested readers to look under the heading "Central Nervous System Stimulants" for any information about the class of "psychostimulants." Respectively, PDR 97 at page 209 enumerates "Central Nervous system stimulants to include amphetamines and appetite suppressants enumerated at the bottom of the 3rd col of page 207, which again encompasses amphetamines. Therefore, contrary to Applicant's arguments, the state of art does not exclude the species, amphetamines, from the generic term psychotropic or mood altering agents.

Moreover, Examiner offers the meaning of the term "psychotropic" as defined by Dorland's Medical Dictionary page 1386. Accordingly the term psychotropic means, "exerting an effect upon the mind, capable of modifying metal activity, usually applied to drugs that affect the mental state." "Mood altering agents" are viewed to simply encompass any agent that alters the mood.

Amphetamine is a drug that falls within such general descriptions. Examiner draws applicant's attention to the attached Goodman & Gillman's, The Pharmacological Basis of Therapeutics 10 ed. copyright 2001, pages 235-237. Accordingly, amphetamines not only provide psychic effects such as elevation of mood, self-confidence or ability to concentrate, but also are therapeutically used for attention deficit hyperactivity disorder as well as obesity. Thus, amphetamine does alter the mood and the state of mind. Therefore, given the broadest reasonable interpretation consistent with the specification and the art, the Examiner has concluded that amphetamines fall within the scope of the term psychotropics and mood altering agents.

6. In response to Applicant's assertion that the instant claims are directed to the use in patients for treatment of schizophrenia, and other psychoses, bipolar disorders, depressive illness, impulse-control disorders and related conditions, Examiner first states that absent a manipulative step, an intended use, does not impart patentability. Moreover, the languages such as "depressive illness" or "impulse control disorders" and "related conditions" do not exclude eating disorders such as "appetite impulse" or attention deficit disorder.

Ritter administers cimetadine, an H2 Antagonist, with an anorexant such as dextroamphetamine, phenteramine or phenmetrazine to treat such conditions as appetite impulse (which falls within the generic term impulse disorders) (see col 1, lines 1-20). Thus, Ritter anticipates such limitations of the instant claims.

7. Applicant also argued that individuals with the types of metnal disorders instantly recited are at much higher rate of substance abuse andd amphetamines are not a choice for such patients. (see Arguments at page 11). In response, Examiner states that Ritter acknowledges such fact and that is at least one reason as to why he adds cimetadine to his regimen. (see col 2, lines 19-col 3, line 20).

Finally claims 37, 39 are merely product claims that fall within the scope of those described in claims 4-5 of Ritter.

Claim Rejections - 35 USC § 103

8. Claims 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bymaster et al EP 0 830 864 in view of Deutsch et al (CNS Drugs, 1997, 8(4): 276-284) and Kaminiski US Patent 5,070,101 and Vivino US Patent 4,220,653.

9. The teachings of Bymaster, Deutsch, Kaminisiski and Vivino are described in the previous Office Action. Their combined teachings meet all elements of the instant claims. Specifically, Deutsch uses his therapeutic combination to treat schizophrenia which falls within the instantly recited psychiatric disorders.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to also use H2-antagnoists such as cimetidine or famotidine in combination with antipshycotics of Bymaster to further reduce appetite and help patient's weight control. Moreover, formulating a composition to contain such ingredients would have also been well within the purview of the ordinary skill in the art.

The ordinary skill in the art would have been motivated to use H2-antagonists with the antipsychotic regimens of Bymaster, because as described by Deutsch and Kaminiski, H2-antagonists are expected to improve schizophrenic symptoms. Therefore, employing weight control benefits of H2-antagonists as described by Vivino would have also been obvious, because the ordinary skill in the art would have had a reasonable expectation of success to observe all therapeutic benefits of such drugs including its appetite reducing effects in the recipient patients.

One of ordinary skill in the art would have further been motivated to formulate a single dosage form containing the psychotropic and H2-antagnoists of choice, because the ordinary skill in the art would have had a reasonable expectation of success to improve patient compliance with a single dosage form.

10. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

11. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, all elements of the claims are describe by the combined teaching of the refrences. Thus, the shortcoming of the primary reference is not by itself amount to a nonobviousness conclusion.

12. In response to applicant's argument that none of the references teach methods of minimizing weight gain, the Examiner states the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Here, Bymaster provides for various types of drugs that can be useful for treatment of schizophrenia. Deutsch and Kaminisi show that that adding an H2-antagonist such as famotidine would improve positive and negative symptoms of schizophrenia. For example, Deutsch describes the therapeutic benefits of famotidine when used as an adjunct therapy for schizophrenia (see abstract, page 277, col 2-page 279; page 282-2nd col-page 283). Kaminiski substantiates the teachings of Deutsch and further states that famotidine improves the negative symptoms of schizophrenia (see abstract, col 3-4). Accordingly, adding an H2 antagonist to a the regimen of a patient undergoing schizophrenia treatment would have been obvious even for other reasons that weight control because Deutsch and Kaminiski, themselves, suggest for such combination.

13. Nevertheless, Examiner has also included Vivino to show that there is ample teaching in the art about the use of cimetidine of reduce weight. (see abstract, col 4, lines 1-44). Thus, in alternative, the teachings of Vivino also provide ample motivation in the art to use a H2-antagonists, such as cimetidine, to effectively reduce appetite.

14. Applicant argues that Vivino does not teach his use of cimetadine with patients who are taking any other medication. (*see* Arguments at page 18, last para). In reply Examiner states that applicant has not provided any evidence showing that the simultaneous use of other drug would render the cimetadine ineffective in suppressing patient's appetite. Thus, for such reasons as set forth above, Examiner maintains the rejection.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SAN-MING HUI
PRIMARY EXAMINER